during 1996. Six therapeutic categories were analyzed. Statistical analyses utilizing multiple regression and analysis of covariance were performed.
RESULTS: Significant associations ($p < 0.001$) were found between plan characteristics and cost of pharmaceuticals. Utilization differed ($p < 0.0001$) among various plan characteristics such as co-payment, mode of payment, formulary status and pharmacy type after controlling for average wholesale price and days supply.
CONCLUSIONS: Results obtained in this study may be helpful in understanding some of the factors associated with cost of pharmaceuticals. For example, the inverse relationship of pharmaceutical cost with eligible days may be helpful in budgeting program costs while the non-significant association of pharmaceutical cost with number of members eligible suggests a lack of importance of group size in negotiating pharmacy benefit contracts. Differences in utilization among various co-payment levels suggest the effectiveness of different co-payment levels in promoting use of generic products. Lower utilization found under capitation may be encouraging to those PBMs accepting a capitation method of reimbursement. Association of closed formularies with higher utilization indicates the importance of adjusting cost data for rebates before evaluating formulary strategies. Finally, differences in utilization between independent and chain pharmacies suggest the importance of careful provider contract negotiation.

OUTCOMES (QUALITY OF LIFE) RESEARCH METHODS ISSUES

POR1

METHODOLOGY FOR DEVELOPING AN INDEX SCORE FOR BOTHERSOMENESS OF ADVERSE EVENTS

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Measures of adverse effect frequency and severity do not accurately depict patients' tolerance to an illness and/or a treatment. The adverse effect frequency model is also a weak predictor for tolerability and compliance. Additional multidimensional variables are required to fully assess the impact on quality of life which can be used as explanatory variables to develop an index for bothersomeness to predict tolerability and hence compliance to therapy.
OBJECTIVE: To develop a methodology for developing an index of bothersomeness.
METHODS: Data on bothersomeness were collected on 50 patients participating in a randomized, placebo-controlled clinical trial. At baseline and final visits, patients completed a questionnaire designed to capture the frequency and bothersomeness of the impact of illness on seven domains of quality of life. Regression methods were used to test the response to bothersome scale for linearity. Additive and predictive models were used to convert the scale to a domain summary scores and hence a composite index for patient bothersomeness. Finally, multivariate models (stepwise procedure) were used with clinical and demographic variables as predictor and composite index derived from additive and predictive methods as dependent variables to estimate observed variance and model fit.
RESULTS: An index scores for bothersomeness was estimated using the additive and predictive methods using data collected over time on 50 patients participating in a clinical trial with the best model fit.
CONCLUSION: The methodology used to calculate the bothersome index can be used in other disease and treatment modalities. The index scores may be used to better describe patients' tolerance, therefore improving the communication between patient and physician when discussing the treatment or illness impact on patients' quality of life.

POR2

PSYCHOMETRIC EVALUATION OF THE PATIENT MEDICATION ADHERENCE QUESTIONNAIRE

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OBJECTIVE: The purpose of this study was to conduct a psychometric evaluation of the Patient Medication Adherence Questionnaire (PMAQ), an HIV-specific instrument designed to assess medication-taking behavior as well as barriers and motivators affecting adherence.
METHODS: The PMAQ was prospectively administered to 410 patients in three studies: 1) a focus group of HIV infected patients ($n = 67$); 2) a cross-sectional observational cohort study ($n = 120$); and 3) a clinical trail, with evaluations at baseline, and weeks 8 and 16 ($n = 223$). The Multitrait/Multi-item Analysis Program-Revised was used to evaluate reliability and validity for each of the five hypothesized PMAQ dimensions: Remembering (REM), Scheduling and Timing (SCH), Physical Effects (PE), Knowledge and Attitudes (KNO), and Social Support (SS).
RESULTS: Results consistent across the studies and across multiple visits within the clinical trial are reported. Cronbach's alpha for four dimensions ranged between 0.43 to 0.73 and between 0.76 to 0.79 for the total score. For the same dimensions, discriminant validity was sufficient to suggest multitrait scaling even though a few items within the dimensions produced weak (<0.40) item-scale correlations. To assess evidence of convergent validity, the same dimensions had scale-scale correlations >0.42. The dimension that did not perform well across these studies was KNO. Given its importance in earlier research, this finding most probably reflects the heterogeneous nature of the items within this dimension. The correlations between REM, SCH, and PE with missed doses were moderate. SS was unrelated to missed doses.
CONCLUSION: Even though the KNO dimension warrants further evaluation, the PMAQ generally demonstrates adequate psychometric properties. It can be used

to assess barriers and motivators to adherence in research settings, and may be predictive of adherence.

POR3

EDMONTON QUALITY ASSESSMENT TOOL FOR DRUG UTILIZATION REVIEWS (EQATDUR): AN INSTRUMENT FOR ASSESSING THE METHODOLOGIC RIGOR OF DRUG UTILIZATION REVIEWS

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OBJECTIVE: The purpose of this project was: 1) to develop an instrument that would provide a systematic approach to evaluating the methodological rigor of published drug utilization reviews (DURs) and DUR programs; and 2) to determine the inter-rater reliability of the instrument's adequacy to discriminate between high and low quality studies.
METHODS: Based upon guidelines that have been accepted for appraising controlled clinical trials and before and after studies, a multidisciplinary panel identified areas where bias could be introduced in the design and conduct of DURs. These areas included selection bias in the sample selection; detection bias in the data collection; selection, detection and exclusion bias if an intervention occurred; and observer bias in the data analysis. Items constituting the criteria to be met were generated for each section. The item content, instructions and scoring system of the EQATDUR were reviewed and revised by clinical and methodological experts. The instrument was piloted and re-tested for inter-rater reliability among raters from four relevant backgrounds using twenty published community and hospital based DUR studies evaluating antibiotic use.
RESULTS: The present version of the EQATDUR includes five sections, each containing two to four criteria to detect the presence of relevant systematic bias. The instrument produced strong inter-rater agreement as represented by an intra class correlation coefficient of 0.76 calculated from the aggregate score for each article.
CONCLUSION: The EQATDUR has the potential to be a useful tool that can assist researchers to determine the strength of the methodological quality of DUR studies.

POR4

LINGUISTIC VALIDATION OF THE SLICE/LIFE QUESTIONNAIRE

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Quality of life (QoL) assessment has become a vital part of international clinical trials. This has made it necessary to produce cross-culturally valid instruments to make comparisons of health status outcomes and pool data across countries. The SLICE/LIFE questionnaire is a 11-item instrument developed in US English to measure the impact of psychological disorders on patients' lives. Prior to use in an international trial including patients with bipolar disorders, the original questionnaire underwent linguistic validation in 16 languages.
METHODS: This process involved the recruitment of a QoL specialist in each country. Two forward translations were produced by two native target language speakers, fluent in English. These were reconciled and back-translated into English. The clarity and appropriateness of the wording were tested in a sample target population, compared and internationally harmonized. The developers clarified concepts underlying problematic items.
RESULTS: This process gave rise to linguistic and cultural issues. These included finding a suitable equivalent for the notion of "impairment" for which different syntactic structures were adopted in most translations. Furthermore, it was impossible to maintain a literal translation of the term "partner" in conjunction with "someone you live with" as the interpretation of the two concepts differed across countries. Finally, as in most cultures it would have sounded insulting to employ a literal translation of "mental illness" in the context of a questionnaire, more adapted expressions needed to be found.
CONCLUSION: A rigorous methodology ensured conceptual equivalence and acceptability of the translations. Psychometric testing will be conducted to ensure reliability and validity of each translation, appropriateness of the questionnaire in each country, and comparability of data across countries.

POR5

EVALUATION OF THE ANALYTICAL HIERARCHY PROCESS (AHP) AS A TOOL IN FORMULARY DEVELOPMENT

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OBJECTIVE: The purpose of this study was to determine the applicability of a multiple criteria decision technique to the evaluation of new drug agents for formulary placement in managed care settings. The Analytic Hierarchy Process (AHP), developed by Dr. Thomas Saaty in 1977, which utilizes pair-wise comparisons among all feasible alternative agents within a hierarchical breakdown of the organization's decision-making preference structure, was utilized to determine the best choice for formulary inclusion.
METHODS: The analytical hierarchy process was used to screen three drug agents used in the treatment of rheumatoid arthritis. This methodology employs a stepwise procedure: 1) Identify alternative drug agents being considered for formulary inclusion; 2) Define organizational preference structure (decision criteria); 3) Quantify the preference of each agent relative to every other agent be-